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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER

SOLOLA, TAOFIQ A

ART UNIT PAPER NUMBER

1626

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/764,373

Applicant(s)

LIPPA ET AL.

Examiner

Taofiq A. Solola

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 24, 26-29, 31-44, 49-52 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 24, 26-29, 31-44 and 49-52 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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Claims 24, 26-29, 31-44, 49-52 are pending in this application.

Claims 1-23, 25, 30, 45-48, 53-56 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, 26-29, 31-44, 49-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to treating or preventing many disorders (claims 24, 26-29) arising through any mechanism, claims 31-44, 49-52. However, the specification disclosure is limited to addictive disorder arising from inhibition of dopamine reuptake. Also, the only assay in the specification relates to the affinity of the instant compound for dopamine receptor. No assay was performed to determine if co administration of the instant compound would lead to partial or complete blockage of the addictive effect of food, alcohol, nicotine, amphetamine, cannabis, cocaine, hallucinogens, inhalants, opioid, etc. The diseases listed in the claims are deemed speculations because they are not supported by biological assays or journal articles. Therefore, the specification lacks adequate support for the claims. Applicant must show possession of the invention by describing it with all the claimed limitations. *Lookwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed Cir. 1997).

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On page 3, last paragraph, the specification recites references that demonstrated co administration of "certain pharmaceutical agents" leads to partial blockage of the effects of the agents. These were incorporated by reference on the last page of the specification. First, the agents are not taught to be the same as the instant compound. Second, such incorporation by reference is not in accordance with the requirement of the MPEP, which states as follows:

A mere reference to another application, publication or patent is not an incorporation of anything therein into the application containing such reference for the purpose of satisfying the requirement of 35 USC 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. MPEP 608.01(p).

If the document is a pending US application: prior to allowance of an application that incorporates essential material by reference to a pending US application, if the referenced application has not been published or issued as a patent, applicant is required to amend the disclosure of the referencing application to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating the amendment consists of the same material incorporated by reference in the referencing application. MPEP 608.01(p).

Claims 24, 26-29, 31-44, 49-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of dopamine reuptake, does not reasonably provide enablement for all the various mechanisms giving rise to the individual disorders listed in claims 31-44, 49-52, nor does it provide enablement for treating or preventing the diseases listed in claims 24, 26-29. The diseases are deemed speculations because they are not supported by biological assays or journal articles. The specification does not enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The claimed methods of use are not believable on their face.

For rejection under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988):

- 1) Breadth of claims.
- 2) Nature of invention.
- 3) State of prior art.
- 4) Level of ordinary skill in the art.
- 5) Level predictability in the art.
- 6) Amount of direction and guidance provided by the inventor.
- 7) Existence of working examples.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breath of the claimed invention involves medicinal chemistry. The nature of the invention is in the field of using the compound for treating or preventing many disorders due to dopamine reuptake inhibition or any mechanism in the body. The state of the prior art is what prior art knows about the nature of the invention. There is no known prior art claiming the use of compounds for treating or preventing the various disorders arising from dopamine reuptake inhibition or any and/or all mechanisms. The level of ordinary skill in the art is high but only in treating the listed disorders, arising from specific mechanism, with specific compound. The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by applicant. In the instant invention the

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predictability is very low and consequently, the need for higher levels of direction and guidance by applicant. However, the amount of direction and guidance provided by applicant is limited to assay on the affinity of the instant compound for dopamine receptor site. There are a very large variety of sources for the listed disorders because different mechanisms are involved. It is well known in the art that the mechanism of a specific disorder would dictate the choice of treatment compound. Additionally, there is no evidence in the specification that established correlation between applicant experiment and all the possible mechanisms giving rise to the various disorders. See Ex parte Mass, 9 USPQ2d 1746, 1987. Therefore, the quantity of experimentation required to use the compound as claimed, based on applicant's limited disclosure would be undue burden because, one of ordinary skill in the art would have to perform significant amount of experiments. By limiting the disorders to those, which have support in the specification, and deleting prevention the rejection would be overcome.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 24, 26-29, 31-44, 49-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For reasons set forth above under 35 USC 112, first paragraph, claims 24, 26-29, 31-44, 49-52 are indefinite. See the Examiner's suggestion above.

Claim 38 is a duplicate of 27, and claim 52 is a duplicate of 29. Under US patent practice duplicate claims must not be in the same application. By deleting the claims the rejection would be overcome.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24, 26-29, 31-44, 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beer et al., US 6,204,284 B1.

Applicant claims a method of using the instant compound for treating various disorders by inhibition of dopamine reuptake. The compound is in its (-) isomeric form substantially free of the corresponding (+) enantiomer.

Determination of the scope and content of the prior art (MPEP §2141.01)

Beer et al., teach a method of using the racemic mixture of the instant compound for treating disorders by inhibition of dopamine reuptake.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of Beer et al., is that applicant uses the (-) isomer substantially free of the corresponding enantiomer instead of racemic mixture by Beer et al.

Finding of prima facie obviousness--rational and motivation (MPEP §2142.2413)

However, the racemic mixture of Beer et al., include the (-) isomer and the phraseology "substantially free" implies the instant compound is not 100 % (-) isomers. The compound of Beer et al., and the instant compound have both isomers except in degrees. Therefore, the instant invention is prima facie obvious from the teaching of Beer et al. One of ordinary skill in the art would have known to use the (-) isomer at the time the invention was made. The motivation is from a well-established principle that one isomer is always more reactive than the

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corresponding isomer or the racemate. Applicant merely did that which is expected. That is, a search for the more active of the isomers. *In re Adamson*, 125 USPQ 233 (1960).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 24, 26-29, 31-44, 49-52 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 25, 30, 45-48

Claims 24, 26-29, 31-44, 49-52 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 25, 30, 45-48 of copending Application No. 10/764,371. In both applications, the claims are drawn to a method of treating diseases by inhibition of dopamine reuptake with the same isomeric compound. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

This is a duplicate of applicant's earlier Application No. 10/764,371. All claims are drawn to the same invention claimed in the earlier application and have been finally rejected on the grounds and art of record in this Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.


TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1626

April 5, 2005